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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,685	07/11/2006	Egon Luther	GK-ZEI-3286/500343.20307	5541

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REED SMITH, LLP
ATTN: PATENT RECORDS DEPARTMENT
599 LEXINGTON AVENUE, 29TH FLOOR
NEW YORK, NY 10022-7650

EXAMINER

LIPITZ, JEFFREY BRIAN

ART UNIT	PAPER NUMBER
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4128

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,685	Applicant(s) LUTHER ET AL.	
	Examiner JEFFREY LIPITZ	Art Unit 4128	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/30/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the monitoring unit (as recited claim 14), the monitoring unit containing one or more interfaces for transferring data (as recited claim 15), an illumination source as a separate structural component (as recited claim 22), a light guide (as recited claim 22), an eyetracker unit (as recited claim 23), an illumination device conceived as a modular unit for retrofit installation (as recited claim 24), the illumination system used in combination with other subassemblies (as recited claim 25), and the illumination unit in a shared housing with other subassemblies (as recited claim 26) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

Art Unit: 4128

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is no description in the instant specification, paragraph [0018] of where and how the light guide connects to the illumination unit or to the illumination source, and how it generates specific illumination patterns.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 13-15 and 20-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Sumiya (US 6,585,723 B1).

Regarding claims 13, 25, and 26, Sumiya discloses an illumination and irradiation unit, which is comprised of an optical system **30** and a corneal shape measurement optical system **10** (Column 3, Lines 35-67; Column 4, Lines 1-17). The corneal shape measurement optical system **10** contains an illumination source **11** and a means for coupling light from the illumination source into the parallel beam path of the observation system **30** (e.g. dichroic mirror **21**). The control unit **40** controls illumination source **11**, the means for generating specific illumination patterns or profiles (e.g. the lens **18**, the scanning mirrors **19** and **20**, and the laser head **26**). The corneal shape measurement optical system **10** is arranged in a shared housing **1** with other optical systems and a control system. The corneal shape measurement optical system **10**, the observation optical system **30**, the laser irradiating optical system **25**, the eyeball position detecting optical system **35**, and the control system **40** are all used in combination with one another to perform corneal surgery (Column 3, Lines 2-25; Figures 1 and 2).

Regarding claims 14-15, where there is a computer **8** comprised of an input unit **41**, a processing unit **42**, a display unit **43**, and an output unit **44**. The processing unit **42** processes signals sent from the photodetector **23**, signals sent from the corneal shape measurement optical system **10** and the inputted irradiation conditions in order to obtain ablation data. The data processed by the processing unit **42** is sent to the control system **40**. Processed data may also be sent to the display unit **43**. In addition to controlling the processing unit **42** and the control system **40**, the computer **8** inherently functions at least at the level of a basic computer, which has more than one

Art Unit: 4128

interface for transferring data (USB ports, data DVD writer, data CD writer, a zip drive, a floppy disc drive, etc...; Column 5, Lines 35-60).

Regarding claim 20, wherein there is the observation optical system **30** and the measurement optical system **10**. The measurement optical system **10** contains a laser source **11**, a lens **12**, a pinhole **13**, a beam splitter **14**, a quarter waveplate **16**, and a dichroic mirror **17**, a lens **18**, scanning mirrors **19** and **20**, and a laser head **26** that generate specific illumination profiles and patterns (Column 6, Lines 47-67).

Specifically, the pinhole **13** can be construed as a diaphragm, and the lenses can be construed as optical filters. All of the aforementioned components are capable of enabling generation of specific illumination patterns and or profiles.

Regarding claim 21, wherein there is a dichroic mirror **21** that enables the optical axis of the measurement optical system **10**, and the laser irradiating optical system **25** to be coaxial with the optical axis of the observation optical system **30**. In addition, the dichroic mirror **21** only permits the transmission of visible light, reflecting the infrared laser beam and the exciter laser beam (Columns 3-4, Lines 62-9). Thus, the dichroic mirror **21** protects the observer from unwanted radiation by filtering out the exciter and infrared laser beams.

Regarding claim 22, wherein there is the observation optical system **30** contains a separate illumination unit **4**. The unit **4** is housed outside the corneal shape measurement unit **10** and is separate from other components of the observation optical system **30**, such as the microscope unit **3**. The illumination unit **4** is comprised of two

Art Unit: 4128

cylindrical barrels that contain the illumination sources **34**. Each of these barrels guides light from these illumination sources **34** to a patient's eye (Column 4, Lines 38-60).

Regarding claim 23, wherein there is an eyeball position detecting optical system **35** and a corneal shape measurement unit **10** (Columns 4-5, Lines 61-34).

Regarding claim 24, wherein there is the observation optical system **30** is conceived as a modular unit for retrofit installation in the parallel beam path of the laser irradiating optical system **25**. The observation optical system **30**, containing the illumination unit **4** and the microscope unit **3**, is attached to the main body **1** containing other subassemblies by the arm portion **2** (Column 3, Lines 3-25). Since several components of the observation optical system **3** and the corneal shape measurement optical system **10** (construed as the illuminating and irradiating unit as claimed) are shared, therefore both modular units are designed for retrofit installation, since each unit requires the other in order to properly function.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sumiya (as discussed supra).

Art Unit: 4128

Regarding claims 16-17, the Sumiya reference DIFFERS in that it does not disclose that the laser beam **11** generates narrow band light around 365 nm as claimed. It however, would have been obvious to one of ordinary skill in the art at the time the invention was made to apply such a wavelength since discovering an optimum range of wavelengths for the laser beam involves only routine skill in the art. In other words, discovering the 365 nm wavelength for the illumination source is not of innovation but of ordinary skill and common sense. *KSR, 550 U.S. (2007)*.

Regarding claims 18-19, the Sumiya reference DIFFERS in that it does not disclose that the laser beam **11** generates narrow band light around 690 nm as claimed. It however, would have been obvious to one of ordinary skill in the art at the time the invention was made to apply such a wavelength since discovering an optimum range of wavelengths for the laser beam involves only routine skill in the art. In other words, discovering the 690 nm wavelength for the illumination source is not of innovation but of ordinary skill and common sense. *KSR, 550 U.S. (2007)*.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY LIPITZ whose telephone number is (571)270-5612. The examiner can normally be reached on Monday to Friday from 7:30-5:00.

Art Unit: 4128

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Khoa Huynh can be reached on 571-272-4888. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JL
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/Khoa D. Huynh/
Supervisory Patent Examiner, Art Unit 4128